

**REMARKS/ARGUMENTS**

Applicants have submitted herewith a Request for Continued Examination under 17 C.F.R. § 1.114. The present amendment is filed in response to the Examiner's Office Action mailed December 6, 2004. In the Office Action, claims 1-28 and 30-54 were rejected. By this paper, claim 22 has been amended. As such, claims 1-28 and 30-54 are pending and should be in condition for allowance. Reconsideration of the above-identified claims is now respectfully requested.

**Rejections under 35 U.S.C. 102(b)**

Claims 1-5, 8-11, 13-18, 20-28, and 30-32 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,964,482 to Gerstel et al.

Applicants submit that Gerstel does not disclose the limitations recited with respect to Claim 1. In particular, Gerstel does not disclose a microneedle array device, as defined in Claim 1, wherein the microneedle array device comprises a plurality of hollow non-silicon microneedles on the major surface of the substrate, wherein the microneedles are located on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface, as articulated in Claim 1. Rather, as is clear from Figures 1-4 of Gerstel, Gerstel discloses projections 12 located on a surface 14 wherein the projections are perpendicular to the surface 14 on which they are located. Therefore, because Gerstel does not disclose all the limitations recited with respect to Claim 1, Applicants request that the rejection under 35 U.S.C. § 102(b) be removed from Claim 1.

Applicants submit that Gerstel does not disclose the limitations recited with respect to Claim 22, particularly as amended. Gerstel does not disclose a microneedle array device comprising a plurality of hollow non-silicon microneedles having a microchannel therethrough that provides communication between at least one input port at a proximal end of each of the microneedles and at least one output port and a channel opening at an opposite distal end, as articulated in Claim 22. As such, Applicants submit that the rejection under 35 U.S.C. § 102(b) should be removed.

Claims 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,728,392 to Miura et al. Applicants submit that Miura does not disclose the limitations recited with respect to Claim 51.

In particular, Miura does not disclose the method of fabricating a microneedle comprising the steps of providing a substrate with a substantially planar major surface, depositing a metal material on the major surface to form one or more bottom walls for one or more microneedles, wherein the microneedles are formed on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface, as articulated in Claim 51.

Accordingly, Miura does not disclose all the limitations recited with respect to Claim 51. As such, Applicants request that the rejection under 35 U.S.C. § 102(b) be removed from Claim 51.

**Rejections under 35 U.S.C. 103(a)**

Claims 12, 19, 33-50 and 54 are rejected under 35 U.S.C. 103(a) as being as being unpatentable over U.S. Patent No. 3,964,482 to Gerstel et al.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See* M.P.E.P. § 2143.

Applicants submit that Gerstel does not teach or suggest all the limitations recited with respect to Claims 33 and 43. In particular, Gerstel does not teach or suggest a microneedle device comprising a single hollow non-silicon microneedle, as articulated in Claim 33. Additionally, Gerstel does not teach or suggest a microneedle device comprising a single hollow elongated shaft, as articulated in Claim 43.

In the Office Action, the Examiner, as a basis for rejecting Claims 33 and 43 stated, "given applicant discloses the embodiments of both multiple and single hollow microneedles, they can be considered equivalents." *See* Office Action, p. 8, ll. 8-9 and 33-35. The teaching or suggestion to make the claimed combination ... must be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Further,

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

See M.P.E.P. § 2144.06. As such, the rejection to Claims 33 and 43 under 35 U.S.C. § 103 are inappropriate and should be removed. As a result, Claims 33 and 43 are in condition for allowance.

#### **Double Patenting**

Claims 51-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,876,582 to Frazier.

Submitted herewith is a Terminal Disclaimer executed by Rajiv K. Kulkarni, Senior Licensing Manager of Assignee, The University of Utah Research Foundation. The Assignee hereby disclaims the terminal part of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term of said U.S. Patent No. 5,876,582 and hereby agrees that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to said U.S. Patent No. 5,876,582, this agreement to run with any patent granted on the above-identified application and to be binding upon the grantee, its successors or assigns.

The Assignee does not disclaim any terminal part of any patent granted on the above-identified application that would extend beyond the term of said U.S. Patent No. 5,876,582 in the event that said U.S. Patent No. 5,876,582 later: (a) expires for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. § 1.321(a); (b) has all claims cancelled by a reexamination certificate; or (c) is otherwise terminated prior to the expiration of its

statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

Claims 1-28 and 30-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,871,158 to Frazier.

Submitted herewith is a Terminal Disclaimer executed by Rajiv K. Kulkarni, Senior Licensing Manager of Assignee, The University of Utah Research Foundation. The Assignee hereby disclaims the terminal part of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term of said U.S. Patent No. 5,871,158 and hereby agrees that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to said U.S. Patent No. 5,871,158, this agreement to run with any patent granted on the above-identified application and to be binding upon the grantee, its successors or assigns.

The Assignee does not disclaim any terminal part of any patent granted on the above-identified application that would extend beyond the term of said U.S. Patent No. 5,871,158 in the event that said U.S. Patent No. 5,871,158 later: (a) expires for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. § 1.321(a); (b) has all claims cancelled by a reexamination certificate; or (c) is otherwise terminated prior to the expiration of its statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

**Conclusion**

In view of the response and amendments submitted herein, Applicants respectfully submit that each of the pending claims is in condition for allowance. Therefore, reconsideration of the rejections is requested and allowance of those claims is respectfully solicited. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that could be clarified in a telephonic interview, the Examiner is respectfully invited to initiate the same with the undersigned attorney.

Respectfully submitted,



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